# Exhibit 9

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## SUMMARY

This was a cGMP/Pre-Approval inspection of an API and finished dosage form drug manufacturer conducted under the following Compliance Programs: CP 7356.002 (Drug Manufacturing Inspections), CP 7356.002I. (Abbreviated API Process Inspections), and CP 7346.832 (Pre-Approval Inspections). It was accomplished under Assignment #9810358/OP ID #7685262 at the request of IOG. This Pre-Approval Inspection (PAI) was performed for [redacted] filed by Prinston Pharmaceuticals, and covered the PAI objectives. All 6 control systems were reviewed: quality, materials, production, facilities & equipment, packaging/labeling, and laboratory.

The previous FDA inspection, conducted on 8/05-09/2013, revealed no reportable objectionable conditions and no form FDA 483, List of Inspectional Observations was issued; classified as NAI. Deficiencies noted were classified as discussion items (7) and were discussed with firm during the inspection and again at the c/o meeting. Management promised to correct/evaluate all discussion items.

The current inspection did not reveal any reportable objectionable conditions and therefore no form FDA 483, List of Inspectional Observations was issued; classified as NAI. Deficiencies noted were classified as discussion items: 1.) quarantined finished batches were not segregated from released finished batches in the F1 warehouse (comingled), although clearly labeled. 2.) inventory logs did not require QA approval sign-offs per entry when put into "quarantine" or "released" status – QA review was done only periodically per each page, and 3.) API identification testing requirements

were not clearly defined in their SOP in regards to specificity, and for APIs received from other firms, requiring individual ID tests for each container sampled during reduced testing. Corrective actions were implemented by the firm during the inspection before the c/o meeting. An approval recommendation for production of *Dabigatran Etexilate* 75mg & 150mg capsules under [redacted] was communicated to management during the close-out meeting and later forwarded to CDER's compliance branch; CDER will make the final determination on the preapproval inspection.

There were no complaints listed in the FACTS database against this firm prior to the start of this inspection. No refusals were encountered and no samples were collected during this inspection. The firm is current with its registration with the FDA as a drug manufacturer.

## ADMINISTRATIVE DATA

| | |
|---|---|
| Inspected firm: | Zhejiang Huahai Pharmaceutical Co., Ltd. |
| Location: | Xunqiao, Linhai, Zhejiang, China 317024 |
| Phone: | +86 576 8501 6001 |
| FAX: | +86 576 8501 6013 |
| Website: | www.huahaipharm.com |
| Mailing address: | Xunqiao, Linhai, Zhejiang, China 317024 |
| Dates of inspection: | 3/23/2015, 3/24/2015, 3/25/2015, 3/26/2015, 3/27/2015 |
| Days in the facility: | 5 |
| Participants: | Michael Y. Philopoulos, Investigator |

Upon arrival on 3/23/2015, I displayed my credentials and exchanged business cards with the firm's departmental management during introductions. The firm's main founder, Mr. Baohua Chen, President/General Manager, introduced himself as the most responsible person for this site and welcomed me to the firm offering full compliance and support during the inspection.

Following the introductions, I briefed management about the purpose of this inspection: a surveillance cGMP inspection and a PAI for *Dabigatran Etexilate* 75mg & 150mg capsules per [redacted]. Management acknowledged the scope of this inspection and then proceeded to give a presentation on the firm's history and operations (**Exhibit 1**).

Note: The API *Dabigatran Etexilate Mesylate*, manufactured at another Huahai API facility (Chuannan site), was not covered during this inspection.

## HISTORY

Zhejiang Huahai Pharmaceutical Co., Ltd. (Huahai) was initially founded in 1989 as a chemical plant, after which in 1997 transformed itself into a pharmaceutical company for manufacturing APIs and Intermediates. In 2002 the firm started manufacturing solid dosage forms for the Chinese market

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|---|---|---|---|---|---|
| [redacted] | Irbesartan + HCTZ Tablets, USP [150/12/5, 300/12.5, 300/25mg (Pending)] | Prinston | I | 0 | 6.9 |
| [redacted] | Paroxetine Tablets, USP (10, 20, 30, 40mg) | Prinston | V | 0 | 16.1 |
| [redacted] | Lisinopril Tablets, USP (2.5, 5, 10mg) | Prinston | V | 0 | 0 |
| [redacted] | Lisinopril Tablets, USP (20, 30, 40mg) | Prinston | V | 0 | 0 |
| [redacted] | Raltegravir Potassium Tablets (ISENTRESS) (400mg) | Merck | I | 0 | 0 |
| [redacted] | Lisinopril Tablets (PRINIVIL) (5, 10, 20mg) | Merck | I | 0 | 0 |

Refer to **Exhibit 2** for detailed lists of all batches and quantities of commercial finished products shipped to the U.S. since August 2013 (last FDA inspection). Refer to **Exhibit 3** for a list of the 30 pending ANDA/NDA products.

In addition to commercial finished products the firm also ships APIs to the U.S. market, such as: Lisinopril Dihydrate USP, Lamotrigine USP, Donepezil HCl USP, and Captopril; lists for approved commercial APIs shipped to the U.S. were not collected.

Adherence to U.S. FDA regulations (U.S. FD&C Act), per PAC 56002/56002F, is required when manufacturing finished drug products/API drug substances for distribution into the U.S. market.

**INDIVIDUAL RESPONSIBILITY AND PERSONS INTERVIEWED**

Key operating personnel and/or main facilitators/contributors during this inspection included, but not limited to:

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| -Baohua Chen | General Manager |
| -Jun Du | Executive Vice President (Main Facilitator/Interpreter) |
| -Pieter Groenewould | Executive Director of Technology, Pharmaceuticals Mfg |
| -Qimao Chen | VP Pharmaceutical Mfg |
| -Chunmin Xu | VP API Mfg & EHS |
| -Cunxiao (Jenson) Ye | Vice President Qualified Person, Pharmacist |
| -Wayne Cheng | Vice Manager, Corporate QA (Translator) |
| -Linda Lin | Director of Regulatory Affairs (Main Facilitator) |
| -Remonda Gergis | QA Senior Director from Prinston Pharmaceutical |
| -Weiding, Bian | Director FDF Mfg (Building F2/Workshop V) |
| -Juan Tao | Associate Director of FDF QA |
| -Youqing Zheng | Manager of FDF QA |
| -Minfa Wang | QC Director |
| -Minli Zhang, Ph.D. | VP API Analytical R&D and QC Manager Formulation |
| -Xiaodi Guo, Ph.D. | VP Institute of Pharmaceutical Research |
| -Xiaoming Liu | Director Assistant, Pharmaceutical Technology |
| -Hu Ye | Deputy Manager of FDF QC |
| -Lingling Sun | Manager of FDF Warehouse |
| -Lianting Ye | Associate Manager of FDF Technical Dept. |